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Liat Tsoref

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P.O. Box 16446

Arlington, VA 22215

EXAMINER

KISH, JAMES M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/042,735	<b>Applicant(s)</b> TSOREF ET AL.	
	<b>Examiner</b> JAMES KISH	<b>Art Unit</b> 3737	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-63 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63 is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/30/03</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed in the Appeal Brief dated January 2, 2007 with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Specification***

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains claim language and is therefore not in narrative form. Correction is required. See MPEP § 608.01(b). Applicant is reminded of the proper content of an abstract of the disclosure.

### ***Claim Objections***

Claims 18, 25-28, 35-36 and 41-61 are objected to because of the following informalities:

Claim 18 is objected to because "said one or more structures" lacks antecedent basis.

Claim 25 is objected to because it is unclear how this subject matter relates to the subject matter of claim 1. Claim 1 is described as a method for measuring bone age while claim 25 predicts adult stature without providing any method steps that would lead to such predictions.

Claims 26 and 31-32 are objected to because "said analysis" is a method step. It is unclear how a method step is being compared to a database. The Examiner suggests that this be changed to, for example, "said at least one effect" or "said determined effect." Furthermore, it is unclear what "a database" would comprise that would allow a correlation with medical images, as described.

Claims 27 and 28 is objected to because "said receiving" has already been claimed as "from said ossification-actuated skeletal structure" in claim 1. It is unclear how it would now be "from a scanning acoustic signal transmitter." Or in the case of claim 28, "from a multi-beam acoustic signal transmitter."

Claim 35 is objected to because the Examiner believes this claim should depend from claim 32 and not claim 26.

Claim 36 is objected to because "said acoustic information" lacks antecedent basis. Furthermore, it is unclear how this claim relates to claim 1. It is unclear whether the estimated bone age, the acoustic signal, the determined effect or a combination of these parameters are used to construct the database. Furthermore, it is unclear how the construction of a database further defines the claimed subject matter. Meaning, it is unclear whether or not the database is actually utilized in the bone age measurement method or if it is a completely separate endeavor.

Claims 41-48 and 60-61 are objected to because it is unclear how these further method steps relate to the measurement of bone age as claimed in the independent claim.

Claim 49 is objected to for being incomplete. The portion of the claim following the line that reads, "a computer system that performs one or more functions of:" is Markush limitations. Therefore, not all of these are required and the computer is not positively being claimed as capable of "estimating said bone age responsive to said received signals." Therefore, this claim is incomplete.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 12-15, 17-21, 24, 27-31 and 33-34** are rejected under 35

U.S.C. 102(e) as being anticipated by Sarvazyan et al. (US Patent No. 6,468,215) -

herein referred to as Sarvazyan. Sarvazyan discloses transmitting acoustic energy (see

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numerals **25** of Figure 2) into an ossification actuated skeletal structure (see numeral **14** of Figure 2) of the body of a subject so that the acoustic energy propagates substantially transverse to the structure (see numeral **25** of Figure 2); receiving an acoustic signal from said ossification-actuated skeletal structure responsive (see the arrow that is within skeletal structure **14** indicating a response) to said transmitted acoustic energy (see numeral 26 of Figure 2); analyzing the acoustic signal to determine at least one effect of said structure on said signal (see Figure 6); estimating the age of the structure from said determined effect (see column 3, lines 40-49).



**Regarding claims 12-13, 15, 17-18, 29-30**, two different acoustic signals are used to provide a measure of bone age. These signals are (1) numerals **25** and **26**, and (2) the arrows designated “Transverse.” The first signal describes a wave that travels along the bone (see column 4, lines 53-55) while the second describes a short ultrasonic pulse that is sent and received by the same probe (see column 5, lines 6-27). The first wave is associated with the bone in that it travels through the bone. The

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second wave is associated with the bone in that it determines a depth at which the bone resides below the skin.

**Regarding claim 14**, column 7, lines 20-21 describes that a comparison can be made with a presumably healthy symmetrical region, thereby incorporating paths within different bones.

**Regarding claims 19-21, 27-28 and 33**, Figure 6 states that the velocity of longitudinal waves and flexural waves are a portion of the acquired information. For claims 20 and 27-28, broadband ultrasound is described at column 4, lines 61-66. The effects of dispersion are described as being avoided and then also exploited at column 7, lines 22-37.

**Regarding claim 24 and 34**, Figure 6 describes a frequency slope of attenuation as acquired information, as well as pulse flight time and of ultrasonic pulse signals propagated in bone.

**Regarding claim 31**, column 7, lines 16-21 describes that diagnostic decision about the bone condition and presence of local lesions is determined on the basis of comparison of the diagnostic index profile graphs with the normal graphs for the particular gender and age.

**Claim 49-52** is rejected under 35 U.S.C. 102(b) as being anticipated by Brandenburger (US Patent No. 4,926,870). Brandenburger discloses an acoustic transmitter (see numeral **26** of Figure 2) and an acoustic receiver (see numeral **28** of Figure 2) positioned facing each other, an electronic movable gantry (see numeral **12** of



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Figure 6) and a computer system (see numeral **18** of Figure 6) that performs one or more functions of: receiving acoustic signals from said receiver responsive to said transmitted signals.

One example of what may be measured with this device is the patella (column 11, lines 30-31), which is an ossification-actuated skeletal structure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 2-11, 22-23, 26, 36-38, 40, 46 and 62** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan alone. Sarvazyan discloses transmitting

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acoustic energy (see numerals **25** of Figure 2) into an ossification actuated skeletal structure (see numeral **14** of Figure 2) of the body of a subject so that the acoustic energy propagates substantially transverse to the structure (see numeral **25** of Figure 2); receiving an acoustic signal from said ossification-actuated skeletal structure responsive (see the arrow that is within skeletal structure **14** indicating a response) to said transmitted acoustic energy (see numeral 26 of Figure 2); analyzing the acoustic signal to determine at least one effect of said structure on said signal (see Figure 6); estimating the age of the structure from said determined effect (see column 3, lines 40-49).

**Regarding claims 2-11**, Sarvazyan states that “Based on the ultrasound parameters and their combinations, quantitative evaluation on bone mineralization (ossification) status, structure and cortical thickness is made (see Abstract).” Therefore, it is obvious that the device and methods of Sarvazyan are intended to be used on ossification-actuated skeletal structures and it would be obvious to one of skill in the art to use said device and methods on any ossification-actuated skeletal structure, as it would only require routine skill in the art to do so.

**Regarding claims 22-23**, It would be obvious to one of skill in the art that different analysis processes and acquired information (as described in Figure 6) would require analysis in both the frequency domain (i.e., pulse spectra, central frequency of spectra, etc.) and the time domain (i.e., pulse flight times, velocity of longitudinal and flexural waves, etc.).

**Regarding claim 26, 36-38 and 40**, Sarvazyan describes that a comparison with normal graphs for particular gender and age is used in the diagnostic steps (column 7, lines 18-20). It is also stated that conventional means of bone quality diagnostics include radiography and planar X-ray, as well as roentgenography (column 1, lines 34-50). Therefore, it would be obvious that these normal graphs would be stored in, for example, a database and that these normal graphs would contain past assessments with conventional and reliable diagnostic information. It would also be obvious to add the newly acquired bone age estimates with corresponding ultrasound signal information to keep the database up-to-date and current.

**Regarding claim 46**, at least two acoustic measurements are acquired to determine the bone characteristics as previously described. These signals are (1) numerals **25** and **26**, and (2) the arrows designated "Transverse."

**Claims 16, 32, 35 and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan as applied to claim 1 above, and further in view of Kaufman et al. (US Patent No. 5,458,130) – herein referred to as Kaufman. Sarvazyan is described above in the rejection of claim 1. However, Sarvazyan does not explicitly describe a formula being used to determine bone characteristics. Kaufman teaches an ultrasonic therapy and assessment apparatus. The apparatus uses ultrasound waves to determine desired bone-related quantities via a neural network (column 3, lines 52-57). The processing flow chart of Figures 2 and 3 illustrate the use of specific equations for processing. It would have been obvious to one of ordinary skill in the art to

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incorporate a neural network for the system of Brandenburger because in order to allow more processing and therefore, more information to be determined from the ultrasound signals.

**Claims 25, 41-45 and 47-48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sarvazyan in view of the Applicant's admitted prior art as described in the specification. The Applicant's Specification on page 1 provides admitted prior art - "In the Greulich and Pyle method a comparison is made between the child's radiograph and the corresponding standard in the Greulich and Pyle atlas." Furthermore, it states, "Bone age assessment in growing subjects is a well-known diagnostic tool that is especially useful in predicting stature and/or growth problems in children, teenagers, and adults." Therefore, it would be obvious to one of skill in the art to use the estimated bone age to diagnose these other attributes.

**Claims 53-56** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandenburger in view of Sarvazyan. Brandenburger discloses an acoustic transmitter (see numeral **26** of Figure 2) and an acoustic receiver (see numeral **28** of Figure 2) positioned facing each other, an electronic movable gantry (see numeral **12** of Figure 6) and a computer system (see numeral **18** of Figure 6) that performs one or more functions of: receiving acoustic signals from said receiver responsive to said transmitted signals. While Brandenburger discusses the degradation of bone structure with age, there is no explicit bone age measurement. Sarvazyan estimates the age of the

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structure (see column 3, lines 40-49) based on similar measured parameters that Brandenburger detects with the apparatus having two transducers facing each other and it would be obvious to combine the teachings of both in order to process the acquired ultrasound data to gain the most information from the signals, including bone age.

**Claims 57-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandenburger in view of Kaufman. Brandenburger discloses an acoustic transmitter (see numeral **26** of Figure 2) and an acoustic receiver (see numeral **28** of Figure 2) positioned facing each other, an electronic movable gantry (see numeral **12** of Figure 6) and a computer system (see numeral **18** of Figure 6) that performs one or more functions of: receiving acoustic signals from said receiver responsive to said transmitted signals. However, Brandenburger does not describe itself as being part of a neural network. Kaufman teaches an ultrasonic therapy and assessment apparatus. The apparatus uses ultrasound waves to determine desired bone-related quantities via a neural network (column 3, lines 52-57). It would have been obvious to one of ordinary skill in the art to incorporate a neural network for the system of Brandenburger because in order to allow more processing and therefore, more information to be determined from the ultrasound signals.

**Claims 59-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brandenburger in view of Sarvazyan as applied to claim 49 above, and further in view of

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the Applicant's admitted prior art as described in the specification. The Applicant's Specification on page 1 provides admitted prior art - "In the Greulich and Pyle method a comparison is made between the child's radiograph and the corresponding standard in the Greulich and Pyle atlas." Furthermore, it states, "Bone age assessment in growing subjects is a well-known diagnostic tool that is especially useful in predicting stature and/or growth problems in children, teenagers, and adults." Therefore, it would be obvious to one of skill in the art to use the estimated bone age to diagnose these other attributes from the determinations of the system of Brandenburger as combined with Sarvazyan

### ***Allowable Subject Matter***

Claim 63 is allowed.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach measuring a first acoustic velocity in a transverse direction to a bone and a second acoustic velocity along a length of the bone, thereafter determining a ratio between the two acoustic velocities, which then provides a measure of bone age.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. While directed toward strength of concrete, Kakuta et al. teaches

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the ratio between velocity of longitudinal and transverse wave velocities to determine strength of concrete.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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